

Freeze-dried Japanese Encephalitis Vaccine

乾燥日本脳炎ワクチン

Freeze-dried Japanese Encephalitis Vaccine is a preparation for injection which is dissolved before use. It contains inactivated Japanese encephalitis virus.

It conforms to the requirements of Freeze-dried Japanese Encephalitis Vaccine in the Minimum Requirements for Biological Products.

Description Freeze-dried Japanese Encephalitis Vaccine is a clear or a slightly whitish turbid and colorless liquid on addition of solvent.

Japanese Gentian

Gentianae Scabrae Radix

リュウタン

Japanese Gentian is the root and rhizome of *Gentiana scabra* Bunge, *Gentiana manshurica* Kitagawa or *Gentiana triflora* Pallas (*Gentianaceae*).

Description Irregular, cylindrical, short rhizome with numerous, slender roots around, and externally yellow-brown to grayish yellow-brown. The root is 10 to 15 cm in length, about 0.3 cm in diameter, and has longitudinal, coarse wrinkles on the outer surface; flexible; fractured surface, smooth and yellow-brown in color. The rhizome is about 2 cm in length, about 0.7 cm in diameter, and has buds or short remains of stems at the top.

Odor, slight; taste, extremely bitter and lasting.

Under a microscope, a transverse section of the young root reveals epidermis, exodermis and a few layers of primary cortex; usually, the outermost layer is endodermis consisting of characteristic cells divided into a few daughter cells, often with collenchyma of 1 to 2 layers contacting the inner side; secondary cortex having rents here and there, and irregularly scattered sieve tubes; vessels arranged rather radially in xylem, sieve tubes existing in xylem; the rhizome has a large pith, rarely with sieve tubes; parenchyma cells contain needle, plate or sand crystals of calcium oxalate and oil drops; starch grains usually absent.

Identification To 0.5 g of pulverized Japanese Gentian add 10 mL of methanol, shake for 20 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of gentiopicroside for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μ L each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, ethanol (99.5) and water (8:2:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): one spot among the spots from the sample solution

and a dark purple spot from the standard solution show the same color tone and the same Rf value.

Total ash Not more than 7.0%.

Acid-insoluble ash Not more than 3.0%.

Powdered Japanese Gentian

Gentianae Scabrae Radix Pulverata

リュウタン末

Powdered Japanese Gentian is the powder of Japanese Gentian.

Description Powdered Japanese Gentian occurs as a grayish yellow-brown powder. It has a slight odor and a lasting, extremely bitter taste.

Under a microscope, Powdered Japanese Gentian reveals fragments of parenchyma cells containing oil droplets and fine crystals, fragments of endodermis and exodermis divided into daughter cells with suberized membrane, and fragments of vessels. Vessels mainly consist of reticulate vessels and scalariform vessels, 20 – 30 μ m in diameter.

Identification To 0.5 g of Powdered Japanese Gentian add 10 mL of methanol, shake for 20 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of gentiopicroside for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μ L each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, ethanol (99.5) and water (8:2:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): one spot among the spots from the sample solution and a dark purple spot from the standard solution show the same color tone and the same Rf value.

Purity Foreign matter—Under a microscope, Powdered Japanese Gentian usually reveals no stone cells and fibers. No starch grains; if any, very few.

Total ash Not more than 7.0%.

Acid-insoluble ash Not more than 3.0%.

Japanese Valerian

Valerianae Radix

カノコソウ

Japanese Valerian is the root and rhizome of *Valeriana fauriei* Briquet (*Valerianaceae*).

Description Obovoid, short rhizome with numerous, fine and long roots; externally dark brown to grayish brown. The root, 10 – 15 cm in length, 0.1 – 0.3 cm in diameter; externally, with fine longitudinal wrinkles; brittle. The rhizome, 1 –

2 cm in length, 1 – 2 cm in diameter, with buds and remains of stem at the crown; hard in texture and difficult to break; flank of rhizome sometimes accompanied with stolons having thick and short or thin, long and extremely small, scaly leaves. Under a magnifying glass, the transverse section reveals a thick, light grayish brown cortical layer, and a grayish brown stele. Odor, strong and characteristic; taste, slightly bitter.

Total ash Not more than 10.0%.

Acid-insoluble ash Not more than 5.0%.

Essential oil content Perform the test with 50.0 g of pulverized Japanese Valerian as directed in the Essential oil content under the Crude Drugs, provided that 1 mL of silicon resin is previously added to the sample in the flask: the volume of essential oil is not less than 0.3 mL.

Containers and storage Containers—Tight containers.

Powdered Japanese Valerian

Valerianae Radix Pulverata

カノコソウ末

Powdered Japanese Valerian is the powder of Japanese Valerian.

Description Powdered Japanese Valerian occurs as a dark grayish brown powder. It is somewhat moist to the touch. It has a strong, characteristic odor and a slightly bitter taste.

Under a microscope, Powdered Japanese Valerian reveals starch grains and fragments of parenchyma cells containing them; fragments of pitted vessels, reticulate vessels, ring vessels, and spiral vessels; fragments of exodermis containing oil droplets and composed of cells suberized and divided into daughter cells; fragments of yellow stone cells from the rhizome and the stolon; and very rarely, some fragments of epidermis and phloem fibers. Starch grains, simple grains 10 – 20 μm in diameter and 2- to 4-compound grains; oil droplets stained red with sudan III TS.

Total ash Not more than 10.0%.

Acid-insoluble ash Not more than 5.0%.

Essential oil content Perform the test with 50.0 g of Powdered Japanese Valerian as directed in the Essential oil content under the Crude Drugs, provided that 1 mL of silicon resin is previously added to the sample in the flask: the volume of essential oil is not less than 0.2 mL.

Containers and storage Containers—Tight containers.

Jujube

Zizyphi Fructus

タイソウ

Jujube is the fruit of *Zizyphus jujuba* Miller var. *inermis* Rehder (*Rhamnaceae*).

Description Ellipsoidal or broad ovoid fruit, 2 – 3 cm in length, 1 – 2 cm in diameter; externally reddish brown with coarse wrinkles, or dark grayish red with fine wrinkles, and both lustrous; both ends slightly dented, with a scar of style on one end and a scar of peduncle on the other; epicarp thin and leather; mesocarp thick, dark grayish brown in color, spongy, soft and adhesive; endocarp extremely hard, fusiform, and divided into two loculi; seeds flat and ovoid. Odor, slight and characteristic; taste, sweet.

Purity Rancidity—Jujube has no unpleasant, rancid odor and taste.

Total ash Not more than 3.0%.

Kainic Acid and Santonin Powder

カイニン酸・サントニン散

Kainic Acid and Santonin Powder contains not less than 9.0% and not more than 11.0% of santonin ($\text{C}_{15}\text{H}_{18}\text{O}_3$: 246.30), and not less than 1.80% and not more than 2.20% of kainic acid ($\text{C}_{10}\text{H}_{15}\text{NO}_4 \cdot \text{H}_2\text{O}$: 231.25).

Method of preparation

Santonin	100 g
Kainic Acid	20 g
Starch, Lactose or their mixture	a sufficient quantity
To make 1000 g	

Prepare as directed under Powders, with the above ingredients.

Description Kainic Acid and Santonin Powder occurs as a white powder.

Identification (1) Shake 1 g of Kainic Acid and Santonin Powder with 10 mL of chloroform, and filter [use the residue for the test (2)]. Distil off the chloroform of the filtrate, and dissolve the residue in 2 mL of potassium hydroxide-ethanol TS: a red color is produced (santonin).

(2) Shake the residue obtained in (1) with 20 mL of warm water, filter, and to 1 mL of the filtrate add 10 mL of water and 1 mL of ninhydrin-L-ascorbic acid TS. Warm in a water bath between 60°C and 70°C for 5 minutes: a yellow color is produced (kainic acid).

Assay (1) Santonin—Weigh accurately about 0.25 g of Kainic Acid and Santonin Powder, add 20 mL of ethanol (95), shake thoroughly for 5 minutes, and filter. Wash the residue with three 10-mL portions of ethanol (95), and filter. Combine the filtrate and the washings, and add ethanol (95) to make exactly 50 mL. Pipet 2 mL of this solution, add ethanol (95) to make exactly 100 mL, and use this solution as the sample solution. Weigh accurately about 0.025 g of santonin for assay, proceed in the same manner as the sample solution, and use the obtained solution as the standard solution. Determine the absorbances, A_T and A_S , of these solutions at 240 nm as directed under the Ultraviolet-visible Spectrophotometry.